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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/751,890

12/27/2000

Glen J. Anderson

1814

9039

30408

7590

05/04/2006

EXAMINER

ZHOU, SHUBO

GATEWAY, INC.

ATTN: PATENT ATTORNEY

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N. SIOUX CITY, SD 57049

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/751,890

Applicant(s)

ANDERSON, GLEN J.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants' amendment and request for reconsideration in the communication filed on 7/25/05 is acknowledged and the amendments entered.

Claims 1, 3-8, 10-17 and newly added claims 19-23 are pending and under consideration.

The rejection of claims 1-18 under 35 U.S.C. 112, first paragraph (enablement rejection) and the rejection under 35 U.S.C. 112, second paragraph, in part, set forth in the previous Office action are hereby withdrawn in view of the amendments to the claims filed 7/25/05.

### *Claim Rejections-35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 8, 10, 12-13, and 16 are rejected under 35 U.S.C. § 102(a) as being anticipated by Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000).

The claims are drawn to a method of providing health care information based on a partial DNA sequence from an individual. The method comprises providing a partial DNA sequence isolated from the individual, analyzing the sequence, archiving information related to existence of at least one medical condition, making information available to the individual, tracking for additional information and making the information accessible by the individual when available.

Patel et al. disclose a method of obtaining and providing genetic information for an individual. The method comprises obtaining blood sample from family members of a patient (proband) with unilateral hemangioblastoma and sequencing the three exons of the VHL genes of their genome into DNA sequences. See page 258 and page 260, left column. The sequence of the VHL gene from each family member is analyzed by searching and comparing with the published VHL gene sequence (GenBank accession number 2282064). The VHL sequences of the proband, his father and brother are interpreted to have a deletion of three base pairs which encodes a phenylalanine in the VHL protein, the mutation of which leads to a syndrome referred to as von Hippel-Lindau disease. See page 258, right column, page 259, Figures 1 and 2, and page 260, left column. These read on the steps of “sequencing”, “interpreting” and “searching” of claim 1. The fact that the information relating to the existence of a medical condition such as retinal hemangioblastoma is published in this article inherently shows that this information is archived and stored in a storage device by the authors and/or by the publishing company, and that the information is available to everyone including the individuals from whom the DNAs were derived. This reads on the steps of “archiving” and “making information .... available ....” of claim 1. Patel et al. tracked for additional information relating to von Hippel-Lindau disease, and found that the disease also includes an array of tumors in different tissues including spinal cord and cerebellum tumors. See page 260, left column. This reads on the “tracking” step of claim 1. The fact that this additional information relating to the existence of medical condition is published in this article inherently shows that this information is made available to, and accessible by, everyone including the individuals from whom the DNAs were derived. This reads on the step of “making said additional information accessible by said individual” of claim 1.

As to claim 3, the fact that the analysis of the VHL sequences in relation to published wild type VHL genes and the association of VHL mutation with von Hippel-Lindau disease is

published in this article inherently shows that this interpretation is archived, at least, in this publication.

As to claim 8, the fact that the analysis of the VHL sequences in relation to published wild type VHL genes and the association of VHL mutation with von Hippel-Lindau disease is published in this article inherently shows that this analysis is accessible for current and for future analysis.

As to claim 10, since the sequences of the proband, the father and the brother all show the same mutation of the VHL gene, i.e. a deletion, the father and brother may have the disease although it was not previously diagnosed. After the sequencing and analysis, Patel et al. detected small tumors from the father and the brother. See page 260, left column. Thus, the information comprises diagnosis, as required in the claim.

As to claim 12, the fact that the additional information relating to the medical condition, i.e. von Hippel-Lindau disease, is published in this article inherently shows that this additional information is archived, at least, in this publication.

As to claim 13, the fact that after the analysis of the sequences and interpretation of the information, the father and brother of the proband, while no tumors were previously diagnosed, were undergone MRI and small tumors were detected, inherently shows that the information of the sequence analysis and association of VHL mutation with von Hippel-Lindau disease has been communicated with health specialists – those who performed the MRI analysis.

As to claim 16, the method by Patel et al. comprises personal data from the individual proband such as the health information of the father, brother, mother, and paternal grandparents. See page 258, right column, and page 260, left column. Since the father and brother also

comprise the same genomic mutation in their VHL genes, the tracking for additional medical conditions also comprises medical conditions associated with their genomes.

Applicants' arguments filed 7/25/05 have been fully considered but not found persuasive. The argument is on the ground that Patel et al. does not teach submitting a partial DNA sequence to a health care provider and does not teach analyzing the sequence including comparing the sequence to a plurality of sequences stored in on a database, etc. This is not persuasive because the authors are from Children's Hospital Los Angeles (see page 258, bottom of left column), and based on the statement by the author that "we screened the von Hippel-Lindau gene in the DNA of the patient and his family members for the presence of mutations as a possible cause of the tumor," (see page 260, left column), it is clear that the authors were health care providers in the sense that they provide diagnosis information for the patients. Patel et al. also disclose that "a three base pair deletion in exon 1 of the von Hippel-Lindau gene was identified in the patient ... and this mutation spans two codons, but because of sequence context it results in an in-frame loss of a phenylalanine residue at position 76 from the predicted von Hippel-Lindau protein product (Genbank Accession No. 2282064)." The fact that the authors cite a GenBank accession No. indicates that they must have analyzed the VHL sequence from the patients against GenBank, which comprise a plurality of sequences including the wild type VHL gene, which is Genbank Accession No. 2282064.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-7, 11, 15, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000), as applied to claims 1, 3, 8, 10, 12-13, and 16 above, in view of Beroud et al. (Nucleic Acids Research, vol. 26, pages 256-258, 1998).

Claims 4-7 and 17 are drawn to a method of providing health care information based on a partial DNA sequence from an individual. The method comprises updating the searching for at least one additional medical condition associated with said DNA sequence by tracking discoveries of genetic variations associated with the additional medical conditions.

As applied to claims 1, 3, 8, 10, 12-13, and 16 above, Patel et al. disclose a method of providing genetic information based on gene sequencing. While Patel et al. do not explicitly recite the phrase “updating” the searching, Patel et al. state that lifelong follow-up is warranted with this disease, and this case demonstrates the value of DNA testing in patients with ocular findings consistent with von Hippel-Lindau disease in the absence of a recognized family

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history. See page 260, left column, last paragraph. This clearly suggests and motivates life long follow up for the disease.

Beround et al. compile the published VHL mutations and their associated medical conditions into a database and provide a computer software to search the database. Beround et al. make the database and software accessible via the internet and world wide web at <http://www.umd.necker.fr>. See Abstract. Beround et al. indicate that the database would be updated and would be made available through the world wide web. See page 269, right column, and page 270, left column.

One of ordinary skill in the art would have been motivated by Patel et al.'s statements to modify Patel et al's method to update the searching of new variations of the VHL sequence in relations to new phenotypes and tracking new discoveries of VHL mutations associated with medical conditions in order to perform the life-long follow-up referred to by Patel et al. by searching the database of Beround et al. using their computer software because the database comprises all the published VHL variations and their corresponding phenotypes, and it would be updated and available to the public.

This updating of searching, interpretation of the genome for more medical conditions, and tracking for new discoveries of genetic variation of the gene associated with new medical conditions by searching the database of Beround et al. read on the limitation recited in claim 9, i.e. interpretation of the genome for additional medical conditions after the initial search is completed, the limitation in claim 11, i.e. the tracking is done electronically, and the limitation in claim 15, i.e. making the information accessible electronically because the database by Beround et al. and the computer software therewith are provided via the internet.



Applicants' arguments filed 7/25/05 have been fully considered but not found persuasive. The argument is essentially the same as that provided for the rejection under 102 above. Applicant argue that the cited references do not teach submitting a partial DNA sequence to a health care provider and does not teach analyzing the sequence including comparing the sequence to a plurality of sequences stored in on a database, etc. This is not persuasive because Patel et al. are from Children's Hospital Los Angeles (see page 258, bottom of left column), and based on their statement that "we screened the von Hippel-Lindau gene in the DNA of the patient and his family members for the presence of mutations as a possible cause of the tumor," (see page 260, left column), it is clear that the authors were health care providers in the sense that they provide diagnosis information for the patients. Patel et al. also disclose that "a three base pair deletion in exon 1 of the von Hippel-Lindau gene was identified in the patient ... and this mutation spans two codons, but because of sequence context it results in an in-frame loss of a phenylalanine residue at dodon 76 from the predicted von Hippel-Lindau protein product (Genbank Accession No. 2282064)." The fact that the authors cite a GenBank accession No. indicates that they must have analyzed the VHL sequence from the patients against GenBank, which comprise a plurality of sequences including the wild type VHL gene, which is Genbank Accession No. 2282064.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.**

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136


(a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

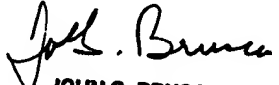
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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Shubo (Joe) Zhou, Ph.D. 

Patent Examiner

 30 April 2016  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER